5

10

15

20

25

30

35

e.g., retrieval of previously saved surgical information, preoperative surgical planning, etc. Image guided surgery using this method is not possible with the computer alone. Full user functionality is enabled only when the proper medium obtained from a software-integrated digital disposable kit, as described below, is inserted into a Standard peripherals the computer. drive on e.g., keyboard, mouse, are also included with kit. display is also provided but is not part of the kit. Wireless peripherals can also be included as part of the kit to enable remote access to the software's graphic user interface. The computer can be included as part of a low cost mobile cart as well.

In accordance with another aspect of the present invention, a software-integrated disposable kit is also sterile which includes (1) instrumented provided disposable surgical tools and (2) a disposable one-time use digital medium, which contains the remaining a portion of the image quided surgery software to enable full user The digital medium will contain at least functionality. (i) a one-time use application specific software module and (ii) descriptive information concerning the surgical tools and other accessories. Further, other accessories, such as cables used to connect the computer to an imaging device e.g., fluoroscope, in sterile condition in sterile packaging which are used in the identified surgical procedure are present in the kit. Other accessories, including but not limited to implants and other associated hardware may be included depending on the application.

In accordance with another aspect of the present invention, sterile instrumented disposable surgical tools are also provided. The tools are in sterile condition in sterile packaging and are used in the identified surgical procedure. The tools are instrumented with markers that can be visualized during an image guided surgery by a tracking system.

5

10

15

20

25

30

35

In accordance with another aspect of the present invention, an application specific software module is contained on the digital medium. The software module can only be used once and will function only when used in conjunction with the portion of the image guided surgery software that resides on the computer.

In accordance with another aspect of the present invention, acoustic, infrared, video camera, or other tracking systems are utilized to determine the location of the instrumented surgical tools. The tracking system can be used to track other accessories e.g., a registration phantom, as well. The tracking system can be incorporated into a separate mobile cart or integrated directly into the operating room infrastructure e.g., lights, ceiling.

At a surgical site, the digital medium is removed from the software-integrated disposable kit and inserted into the computer. The software which resides on the computer in conjunction with the software on the digital medium, processes electronic medical diagnostic images, registers the acquired images to the patient's anatomy, registers the acquired images to any other acquired imaging modalities e.g., fluoroscopy to CT, MRI. The location of the instrumented surgical tool(s) is tracked by simultaneously updating the tool's virtual representation in the image(s), or any combination or subset thereof, with movement of the tool(s) in physical space. After the surgery, the digital medium and the surgical tool(s) are disposed of as they are disposable and can only be used once.

One advantage of the present invention resides in low or no capital cost to hospital and medical facilities for the equipment.

Another advantage of the present invention is that it enables automatic upgrade of the image guided surgery software and of the specifications, descriptions, and characteristics of the surgical tools residing on the computer upon insertion of the digital medium. 5

15

20

25

Yet another advantage of the present invention is the assured sterility of the surgical tools, accessories, and any other components of the system contained in the software-integrated disposable kit, which enter the sterile field.

Another advantage of the present invention is the assured sharpness and reliable maintenance of any other quality aspects of the surgical tools and guides.

Another advantage includes simplified patient 10 billing.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

FIGURE 1 is a perspective view of a mobile cart in combination with a computer with peripherals including but not limited to a joystick, a display, accessories including but not limited to cables, and a tracking system in accordance with the present invention;

FIGURE 2 is a perspective view of a software-integrated disposable kit in accordance with the present invention; and,

FIGURE 3 is a diagrammatic illustration of a schematic for the computer in accordance with the present invention.

Detailed Description of the Preferred Embodiments

With reference to FIGURE 1, one embodiment of the invention mentioned herein includes a computer 10 that is mounted in a mobile cart 12 or other convenient